COLD RELIEF MULTI-SYMPTOM, DAYTIME, NIGHTTIME, NON-DROWSY-acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, guaifenesin, phenylephrine hcl Family Dollar Services Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Family Wellness 44-503A473C

Active ingredients (in each caplet) (Daytime Cold & Flu Severe)

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant

Active ingredients (in each caplet) (Nighttime Cold & Flu Severe)

Acetaminophen 325 mg Chlorpheniramine maleate 2 mg Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer Antihistamine Cough suppressant Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- cough
- sore throat
- headache
- nasal congestion
- minor aches and pains
- sinus congestion and pressure (Nighttime only)
- sneezing and runny nose (Nighttime only)

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive (Daytime only)
- helps clear nasal passages (Nighttime only)
- relieves cough to help you sleep (Nighttime only)
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- diabetes
- thyroid disease
- heart disease
- glaucoma (Nighttime only)
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- high blood pressure
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- a breathing problem such as emphysema or chronic bronchitis (Nighttime only)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (Nighttime only)

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children (Nighttime only)
- marked drowsiness may occur (Nighttime only)
- avoid alcoholic beverages (Nighttime only)
- use caution when driving a motor vehicle or operating machinery (Nighttime only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts. These could be signs
 of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Read each section carefully. Do not take DAYTIME and NIGHTTIME products at the same time.

Directions

- do not take more than directed
- adults and children 12 years and over
- take 2 caplets every 4 hours
- swallow whole do not crush, chew, or dissolve
- do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients (Daytime only)

corn starch, crospovidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone,

silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Inactive ingredients (Nighttime only)

corn starch, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

Family Wellness™

COMPARE TO THE ACTIVE INGREDIENTS IN TYLENOL® COLD + FLU SEVERE NIGHT*

MULTI-SYMPTOM COLD RELIEF

Acetaminophen

Dextromethorphan HBr Guaifenesin Phenylephrine HCl

DAY

Actual Size

- Pain Reliever/Fever Reducer
- Cough Suppressant
- Expectorant
- Nasal Decongestant

Acetaminophen

Chlorpheniramine maleate Dextromethorphan HBr Phenylephrine HCl

NIGHT

Actual Size

- Pain Reliever/Fever Reducer
- Antihistamine
- Cough Suppressant
- Nasal Decongestant

OTC

network

16 DAY Caplets: **8 Night** Caplets:

TOTAL 24 CAPLETS NDC 55319-507-08

100% satisfaction guarantee or your money back

DISTRIBUTED BY: MIDWOOD BRANDS, LLC 500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

NOT 100% SATISFIED? Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® COLD + FLU SEVERE Day & Tylenol® COLD + FLU SEVERE Night.

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING



Family Wellness 44-503A473

Part 2 1 BLISTER PACK

COLD RELIEF MULTI-SYMPTOM, DAYTIME, NIGHTTIME, NON-**DROWSY**

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, quaifenesin, phenylephrine hcl

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-507 **Packaging Marketing Start Marketing End Item Code Package Description Date** Date NDC:55319-507- 1 in 1 CARTON; Type 0: Not a Combination 08/04/2005 **Quantity of Parts** Part # **Package Quantity Total Product Quantity** Part 1 2 BLISTER PACK 16

8

Part 1 of 2

COLD RELIEF DAYTIME

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

Route of Administration

ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	yellow	Score	no score	
Shape	OVAL	Size	19mm	
Flavor	MINT	Imprint Code	44;503	
Contains				

Pa	ckaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part341	08/04/2005				

Part 2 of 2

COLD RELIEF NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl tablet, film coated

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg			
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	2 mg			
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg			
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg			

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C BLUE NO. 2ALUMINUM LAKE (UNII: 4AQJ3LG584)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	17mm	

Flavor		MINT	Imprint Code		44;473
Contains					
Packaging					
# Item Code	Pa	ickage Desci	ription	Marketing Start Date	Marketing End Date
	in 1 BLISTER oduct	PACK; Type 0: No	ot a Combination		
		_			
Marketing	Inform	ation			
Marketing Category	Appl	ication Numb Citat	er or Monograph ion	Marketing Start Date	: Marketing End Date
OTC monograph fi	inal part341			07/21/2005	
Marketing Information					
Marketing Category	Appl	ication Numbe Citat	er or Monograph ion	Marketing Start Date	: Marketing End Date
OTC monograph fi	inal part341			08/04/2005	

Labeler - Family Dollar Services Inc (024472631)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(55319-507, 55319-507)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(55319-507, 55319-507)

Revised: 10/2021 Family Dollar Services Inc